June 17, 2023

VINNO Technology (Suzhou) Co., Ltd.
℅ Cordelia Liu
Regulatory Registered Engineer
5F Building A, 4F Building C No. 27 Xinfa Rd.
Suzhou Industrial Park
Suzhou, Jiangsu 215123
CHINA

Re: K223920
Trade/Device Name: VINNO G50, VINNO G55, VINNO M50, VINNO E30, VINNO X5, VINNO X6, VINNO X7, VINNO M55, VINNO E35, VINNO X65, VINNO X55, VINNO X35, VINNO G55E, VINNO G55P, VINNO M55E, VINNO M55P, VINNO E35E, VINNO E35P
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: April 12, 2023
Received: May 17, 2023

Dear Cordelia Liu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Yanna S. Kang -S

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223920

Device Name
VINNO G50、VINNO G55、VINNO M50、VINNO E30、VINNO X5、VINNO X6、VINNO X7、VINNO M55、VINNO E35、VINNO X65、VINNO X55、VINNOX35、VINNO G55E、VINNO G55P、VINNO M55E、VINNO M55P、VINNO E35E、VINNOE35P

Indications for Use *(Describe)*
The device is a general purpose diagnostic ultrasound system intended for use by appropriately trained healthcare professionals in a hospital setting. The device is intended for ultrasound imaging, measurement, display and analysis of the human body and fluid.

This device is indicated for Abdominal; Fetal/Obstetrics; Gynecology;Transvaginal; Urology(including prostate); Transrectal; Cardiac(adult and pediatric); Peripheral Vascular; Small Organs/Parts(thyroid, breast, testicle, Musculo-skeletal Conventional and Superficial); Pediatrics(including neonatal cephalic); and Adult Cephalic diagnostic Ultrasound applications.

The operating modes supported by the device are B mode, Harmonic mode, M mode, Color Flow mode, Power-Doppler mode, Pulsed Wave Doppler mode, Continuous Wave Doppler, 3D mode, 4D mode, Spatio Temporal Image Correlation mode, Tissue Doppler mode, Tissue Velocity Imaging mode, Elastography mode and Contrast Agent Imaging mode.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 5 510(k) summary K223920

I Submitter

Device submitter: VINNO Technology (Suzhou) Co., Ltd.
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Date of written: 16 Jun 2023

II Device

Trade Name of Device: VINNO G50、VINNO G55、VINNO M50、VINNO E30、VINNO X5、VINNO X6、VINNO X7、VINNO M55、VINNO E35、VINNO X65、VINNO X55、VINNO X35、VINNO G55E、VINNO G55P、VINNO M55E、VINNO M55P、VINNO E35E、VINNO E35P
Regulation name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR 892.1550
Regulatory Class: II
Product code: IYN, IYO, ITX

III Predicate Devices

Trade name: HS40 Diagnostic Ultrasound System
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR 892.1550
Regulatory Class: II
Product code: IYN, IYO, ITX
Premarket Notification: k180409

IV Device description

The VINNO G50、VINNO G55、VINNO M50、VINNO E30、VINNO X5、VINNO X6、VINNO X7、VINNO M55、VINNO E35、VINNO X65、VINNO X55、VINNO X35、VINNO G55E、VINNO G55P、VINNO M55E、VINNO M55P、VINNO E35E、VINNO E35P ultrasound devices are professional digital color ultrasonic diagnostic apparatus. It transmits ultrasound waves into the body tissues and displays the echo images of the tissues and

blood flow accordingly.

V Indications for use

The device is a general purpose diagnostic ultrasound system intended for use by appropriately trained healthcare professionals in a hospital setting. The device is intended for ultrasound imaging, measurement, display and analysis of the human body and fluid.

This device is indicated for Abdominal; Fetal/Obstetrics; Gynecology;Transvaginal; Urology(including prostate); Transrectal; Cardiac(adult and pediatric); Peripheral Vascular; Small Organs/Parts(thyroid, breast, testicle, Musculo-skeletal Conventional and Superficial); Pediatrics(including neonatal cephalic); and Adult Cephalic diagnostic Ultrasound applications.

The operating modes supported by the device are B mode, Harmonic mode, M mode, Color Flow mode, Power-Doppler mode, Pulsed Wave Doppler mode, Continuous Wave Doppler, 3D mode, 4D mode, Spatio Temporal Image Correlation mode, Tissue Doppler mode, Tissue Velocity Imaging mode, Elastography mode and Contrast Agent Imaging mode.

VI Comparison of technological characteristics with the predicate devices

The VINNO G50、VINNO G55、VINNO M50、VINNO E30、VINNO X5、VINNO X6、VINNO X7、VINNO M55、VINNO E35、VINNO X65、VINNO X55、VINNO X35、VINNO G55E、VINNO G55P、VINNO M55E、VINNO M55P、VINNO E35E、VINNO E35P ultrasound devices have the same technological characteristics and fundamental design as the predicate devices. The VINNO G50、VINNO G55、VINNO M50、VINNO E30、VINNO X5、VINNO X6、VINNO X7、VINNO M55、VINNO E35、VINNO X65、VINNO X55、VINNO X35、VINNO G55E、VINNO G55P、VINNO M55E、VINNO M55P、VINNO E35E、VINNO E35P ultrasound devices and the predicate device are all general purpose ultrasound devices designed to provide real-time images for diagnosis. The differences between The VINNO G50、VINNO G55、VINNO M50、VINNO E30、VINNO X5、VINNO X6、VINNO X7、VINNO M55、VINNO E35、VINNO X65、VINNO X55、VINNO X35、VINNO G55E、VINNO G55P、VINNO M55E、VINNO M55P、VINNO E35E、VINNO E35P ultrasound devices and predicate devices do not alter suitability of the proposed device for its intended use.

See the following table for details on the comparison of technical features with the predicate device:

Device feature	VINNO G50, VINNO G55, VINNO M50, VINNO E30,	SAMSUNG MEDISON HS40 k180409 (predicate device)

	VINNO X5, VINNO X6, VINNO X7, VINNO M55, VINNO E35, VINNO X65, VINNO X55, VINNO X35, VINNO G55E, VINNO G55P, VINNO M55E, VINNO M55P, VINNO E35E, VINNO E35P (subject device)	
Indications for use	The device is a general purpose diagnostic ultrasound system intended for use by appropriately trained healthcare professionals in a hospital setting. The device is intended for ultrasound imaging, measurement, display and analysis of the human body and fluid. This device is indicated for Abdominal; Fetal/Obstetrics; Gynecology;Transvaginal; Urology(including prostate); Transrectal; Cardiac(adult and pediatric); Peripheral Vascular; Small Organs/Parts(thyroid, breast, testicle, Musculo-skeletal Conventional and Superficial); Pediatrics(including neonatal cephalic); and Adult Cephalic diagnostic Ultrasound applications.	The HS40 Diagnostic Ultrasound System and transducers are intended for diagnostic ultrasound imaging and fluid analysis of the human body. The clinical applications include: Fetal/Obstetric,Abdominal,Gynecology,Intra-operative,Pediatric,Small Organ,Neonatal Cephalic,Adult Cephalic,Trans-rectal, Trans-vaginal,Muscular-Skeletal(Conventional,Superficial), Urology,Cardiac Adult,Cardiac Pediatric and Peripheral vessel

	The operating modes supported by the device are B mode, Harmonic mode, M mode, Color Flow mode, Power-Doppler mode, Pulsed Wave Doppler mode, Continuous Wave Doppler, 3D mode, 4D mode, Spatio Temporal Image Correlation mode, Tissue Doppler mode, Tissue Velocity Imaging mode, Elastography mode and Contrast Agent Imaging mode.	
User qualification	Qualified healthcare professionals	Qualified physicians or sonographers
Physical Specification	Width: 605mm; Depth: 875mm; Height: 1260mm; Weight: Basic unit without accessories approx: 60kg; Control panel: Ergonomic designed control panel with interactive back-lighting; +60°to - 60°horizontal swivel together with touch panel and monitor; Number of Probes:4	Height: 1354~1620mm; Width: 520mm; Depth: 730mm; Weight:51Kg(without accessories); Weight: Approx. 57Kg(with safe working load)
Patient contact materials	Probe housing: ABS, Probe lens: Silicon rubber Comply with ISO10993 series	Probe housing: ABS Probe lens: Silicon rubber Comply with ISO10993 series
Operating modes	B mode, Harmonic mode, M mode, Color Flow mode, Power-Doppler mode, Pulsed Wave	Mode (2D), Color Doppler Mode (C), Pulse Wave Doppler (PWD), Continuous Wave Doppler(CWD): Steered / Static,

	Doppler mode, Continuous Wave Doppler, 3D mode, 4D mode, Spatio Temporal Image Correlation mode, Tissue Doppler mode, Tissue Velocity Imaging mode, Elastography mode, Contrast Agent Imaging mode.	Power Doppler Mode (PD), S-Flow ™ Mode, M-Mode (M), Anatomical M Mode,Single/Dual/Quad Mode, Volume Mode TDI/TDW, ElastoScan Mode
Operating controls	Gain, Frequency, Focus Position, TView, L/R, Full screen, VT issue, Dynamic Range, Line density, VSharpen, Image Angle, Persistence, Gray Filter, Smooth, Focus Width, Acoustic Power, Biopsy, VNear, EdgeEnhance, NeedleEnhance, TI, SGC, Depth,TGC slides controls, B Steer, 2D Automatic Optimization, Harmonic Imaging,VFusion, Vspeckle, VSharpen, U/D, Trapezoid,PView,Map, M mode, Sweep Speed, Curve MAM, PRF, Wall Filter, Packet Size, Color Level, Invert, Color Map, Sync Display, Radiant Flow, Sync ROI,Base Line, Flash	Dynamic Range,Frame Average, Frequency,Gain , Harmonic, Pulse Inversion Harmonic (Probe dependent),Line Density, Power, Reject, Scan Area, TGC, Write Zoom, -MultiVision (Probe Dependent), Beam Steering (Probe Dependent), Trapezoid (Probe Dependent), Free Angle Plane, Filter, PRF (Scale), Sample Volume Angle, Sample Volume Position, Sample Rate, Sweep Speed, Chroma Map, Gray Map, Image Size, ClearVision, M Mode Map, Alpha Blending, Blending Level, Enhancement, Hide Color, Balance, Baseline,Trace Direction, Trace Method, Sound

	Reduction,Persistence,Transparency, Steer, Biplane probe,	
Measurements	Abdominal, Obstetrics, Gynecology, Urology, Pediatrics, Cardiac, Vessel, Small organs(e.g. breast, testes, thyroid) , Trans-cranial Doppler, Fetal heart	Caliper, Abdomen, Cardiac, Vascular, Gynecology, Obstetrics, Fetal Heart, Urology, MSK, Small Parts, Pediatric
Comments	Comments and bodymarks	Comments and bodymarks
Probe types	Convex array Linear array Phased array 4D Probe Endocavity Micro Convex Volume Convex	Convex array Linear array Phased array Endo-Cavity Micro-Convex Array Pencil Volume Probe
Display monitor	21.5/23.8 inch LCD monitor	21.5 inch LED monitor
Acoustic output	Comply with Track 3 limits: Ispta.3≤720mW/cm^2 MI≤1.9	Comply with Track 3 limits: Ispta.3≤720mW/cm^2 MI≤1.9
Conformity standards	IEC6061-1 IEC60601-1-2 IEC60601-2-37 IEC60601-1-6 IEC62366 NEMA UD 2	IEC6061-1 IEC60601-1-2 IEC60601-2-37 IEC60601-1-6 IEC62366 NEMA UD 2
Peripherals	Printers, USB DVDRW, ECG, S-Video output Cable, Buletooth/Wireless adapter, Foot switch, HDMI, Monitor	S-Video Output, HDMI, Printers, DVD, USB, Foot switch, ECG, Monitor

VII Performance data

The following performance data were provided in support of the substantial equivalence

determination.

Biocompatibility testing

Biocompatibility of the probes was evaluated in accordance with ISO 10993-1:2009. All evaluation acceptance criteria were met

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Ultrasound System. The system complies with the IEC 60601-1 and IEC 60601-2-37 for safety and the IEC 60601-1-2 for EMC.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern.

Acoustic output testing

Acoustic output testing was performed according to NEMA UD2 and IEC60601-2-37.

VIII Conclusion

The VINNO G50、VINNO G55、VINNO M50、VINNO E30、VINNO X5、VINNO X6、VINNO X7、VINNO M55、VINNO E35、VINNO X65、VINNO X55、VINNO X35、VINNO G55E、VINNO G55P、VINNO M55E、VINNO M55P、VINNO E35E、VINNO E35P ultrasound devices are substantially equivalent to their predicate device. The non-clinical testing demonstrates that the device is as safe, as effective and performs as well as the legally marketed device.

Comparison:

-Both the subject and predicate device are used for the diagnostic ultrasonic imaging and fluid flow analysis. The indications for use of the subject devices - VINNO G50, VINNO G55, VINNO M50, VINNO E30, VINNO X5, VINNO X6, VINNO X7, VINNO M55, VINNO E35, VINNO X65, VINNO X55, VINNO X35, VINNO G55E, VINNO G55P, VINNO M55E, VINNO M55P, VINNO E35E, VINNO E35P are covered by the indications for use of the predicate device. Ophthalmic and Trans-esoph are not intended to be used.

-The subject and predicate device employ the same fundamental scientific technology and have similar physical designs.

-The operating modes of the subject devices are covered by the operating modes of the predicate device Diagnostic Ultrasound System.

-The operating controls are similar as the predicate device.

-The measurement part are also similar with the the predicate device.

-The probe types are the same as the predicate device HS40 Diagnostic Ultrasound

System (K180409).
-The display monitor are almost similar with the predicate device.
-The contact materials are similar as those of the predicate device, and all passed the biocompatibility test respectively.
-The subject and predicate device are all track 3 devices meeting the maximum limits of the acoustic output parameters.
-The subject and predicate device conform to the same electrical safety standards.
-The subject and predicate device support similar interfaces with accessories.